

I. REMARKS

Claims 1 – 20 and 22 are pending in the above-identified application. Claim 21 is cancelled herein.

Independent Claims 1, 20 and 22 are amended herein to limit the claims to "therapeutically" active proteins, i.e., proteins and peptides that are administered to a patient as the active drug substance to treat a disease or condition. Support for this amendment is found at page 8 and page 9, lines 1-8 of the specification. The independent claims have additionally been amended to make it clear that the stable formulations of the invention are liquids.

Independent Claims 1, 20 and 22 and dependent Claim 3 are amended herein to exclude enzymes from the therapeutically active proteins and peptides that are useful in the liquid formulations of the invention.

Amendments to the claims other than those discussed hereinabove are "housekeeping" in nature and are matters of style not substance.

Applicants thank Examiner for the courtesy extended to Applicants' attorney in faxing a copy of the non-final Office Action (Paper 7) to Attorney Coburn. The original Office Action dated March 21, 2003 was not received by Applicants and is presumed to have been lost in the mail.

Accompanying this Response to the Office Action dated March 21, 2003 is a Petition for Extension of Time Under 37 CFR 1.136(a) along with payment of the required fee.

II. ARGUMENTS

A. Rejection Under 35 USC § 102(b)

Claims 1-3, 8, 12 and 17-19 are rejected under Section 102(b) as being anticipated by Humphreys et al (US 5,385,685). Examiner contends that Humphreys teaches a liquid detergent composition comprising the following:

Component	% by Weight
glyceroglycolipid	5 - 70
enzyme	0.01 - 5
enzyme stabilizer	0.01-15
H ₂ O	qs

Humphreys' ideal liquid detergent composition as described at col 9, lines 43-51 requires the presence of an enzyme such as proteases, lipases, amylases, and cellulases. These enzymes are key to the cleaning ability of the laundry detergent as it is these enzymes that breakdown fats, starches, and proteins that typically stain laundry. The liquid formulations of Applicants' invention do not contain an enzyme. Accordingly, Humphreys does not anticipate Applicants claimed invention.

Claim 22 is rejected under Section 102(b) as being anticipated by Chaplygina et al (SU 818619; 4/7/81). Examiner contends that Chaplygina teaches a composition comprising the following:

Component	% by Weight
protein hydrolyzate	20 - 25
glucose	20 - 30
Ethanol	4 - 6
peppermint extract	1 - 1.4
disodium phosphate	0.08 - 0.12
saccharin	0.03 - 0.05
H ₂ O	qs

Applicants do not presently have a copy of the reference; however, using the Delphion database, Applicants were able to ascertain that the title of the abstract is "Dietotherapy Composition". Based on the title, Applicants presume that the composition of Chaplygina is a liquid dietary supplement that is taken by mouth.

Protein hydrolyzates are widely used in nutritional supplements, infant formulas, sports drinks and meal substitutes for weight reduction programs. The hydrolyzate is produced when a protein e.g., whey protein or soybean protein, is subjected to controlled hydrolysis to produce

food grade hydrolyzates. Hydrolysis is a chemical process where acids or enzymes are used to break the peptide bonds of the protein resulting in smaller polypeptides and peptides. The resulting hydrolyzate is a mixture of peptides, polypeptides and even whole protein. While a protein hydrolyzate may enhance health through its nutritional action, it is not an "active drug substance" as that term is understood by one skilled in the pharmaceutical or the dietetic arts.

The composition of Chaplygina does not contain a derivatized carbohydrate as required by Applicants liquid formulations. Glucose and saccharin are sugars but they are not derivatized. Further, Applicants believe that there is no teaching in the Chaplygina reference that suggests any derivatized carbohydrate.

In order to anticipate a claimed invention, a reference must fairly disclose each and every element of the claimed invention in the four corners of the reference. The Chaplygina reference does not meet this test and thus does not anticipate Claim 22 of Applicant's invention.

B. Rejection Under 35 USC §103(a)

The presently pending claims are rejected under Section 103(a) as being obvious over Humphreys et al. Examiner contends that it would have been obvious to one having ordinary skill in the art to modify the composition of Humphreys to arrive at the liquid formulation claimed herein. The problem with Examiner's contention is that it ignores the question of who is the skilled artisan.

The invention of Humphreys is in the field of liquid detergents and not pharmaceuticals. A skilled pharmaceutical formulation chemist would consider Humphreys to be non-analogous art and would not look to Humphreys at all. The mere fact that the prior art may be modified in the manner suggested by Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.

The Examiner has used Applicants claimed invention as a template to arrive at the determination of obviousness. "It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious". In re Fritch, 23 USPQ 2d at 1783-84 (Fed. Cir. 1992). It is well settled that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art ..." to arrive at the claimed invention and thus, render it obvious. In re Fine, 5 USPQ 2d, 1596, 1600 (Fed. Cir. 1988).

Claim 22 is rejected under 35 U.S.C. §103(a) as being obvious over JP 511116806 10/14/76. Applicants do not have a copy of this reference and the following remarks are made based on Examiner's conclusions of what this art teaches. Examiner asserts that the Japanese reference teaches a liquid detergent comprising a protein, sugars, and solvents.

If the protein of the Japanese reference is an enzyme then the reference teaches no more than what is taught by Humphreys. All of Applicants arguments made herein regarding Humphreys apply as well to the Japanese reference. Further, Applicants believe that the Japanese reference does not disclose the use of the derivatized carbohydrate compounds taught by Applicants.

Based on the amendments and arguments made herein, it is respectfully asserted that Claims 1-20 and 22 directed to a stable liquid formulation of a therapeutically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment are in condition for allowance. Examiner is respectfully requested to withdraw the rejections under 35 USC §102(b) and 35 USC §103(a) and to issue a Notice of Allowance.

Respectfully submitted,

Dated: September 22, 2003

By: Patricia A. Coburn
Patricia A. Coburn

Registration No. 28,594
BattellePharma, Inc.
1801 Watermark Dr., Suite 100
Columbus, OH 43215-1037
(614) 340-2358 Office
(614) 340-2320 Fax